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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,845	06/27/2001	Xavier Paliard	1681.002	3705

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/894,845	PALIARD, XAVIER	
	Examiner	Art Unit	
	J. E. Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,7,12,15-19,41 and 43-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,12,15-19,41 and 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/18/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 12/18/2008.

The amendment filed 12/18/2008 is acknowledged and has been entered.

Claims 1-3, 6, 7, 12, 15-19, 41, 43-46 are currently pending in the application and are addressed herein.

1. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/18/2008 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3, 6, 7, 12, 15-19, 41, 43-46 are rejected under 35 U.S.C. 103(a) as being obvious over Gorczynski et al. (Cellular Immunology, 1995, previously of record) in view of

U.S. Patent No. 6,582,692 (Podsakoff et al.; previously of record), Wakita et al. (JBC, 1998, previously of record), and Lee et al. (Vaccine, 2000; cited by Applicants, see 12/18/08 IDS).

It is noted that Lee et al. is applicable as prior art only under 35 U.S.C. 102(a) (i.e. Lee was published less than 1 year prior to the instant effective filing date and different entity). Thus Applicants may overcome the instant rejection by filing a proper Declaration under 35 U.S.C. 1.131 or 1.132.

Gorczynski teaches the general concept that animals that are immunologically tolerant to an immunogen can be made by producing the sustained presence of a tolerance inducing immunogen in the liver of the animal. Specifically, Gorczynski teaches a method of making a mouse (i.e., a rodent) that is tolerant to skin allografts by injecting cells (i.e., an immunogen) into the portal vein of the mouse (e.g., see abstract; page 224; page 225, column 1, etc.).

Gorczynski, however, does not teach that the immunogen is the p214K9 peptide, wherein the p214K9 peptide is encoded by a nucleic acid that is delivered by portal vein injection.

The prior art teaches that portal vein delivery of an adeno-associated viral particle encoding a specific protein results in the sustained expression of encoded protein in the liver of the animal (e.g., see Podsakoff et al.). Furthermore, the prior art also recognizes that a transgenic animal that expresses specific HCV genes in its liver can be used as a powerful tool to investigate the immune responses and pathogenesis of HCV infection. (e.g., see Wakita et al. 1998, it is noted that the mice of Wakita are transgenic mice and as long as the transgene was present it would be expressed in the animal).

Podsakoff et al. specifically teach the sustained expression of a gene of interest in the liver of an animal using an adeno-associated viral vector that expresses the gene of interest using

the liver-specific alpha-1 antitrypsin promoter and ApoE enhancer wherein the adeno-associated viral particle is delivered to the liver by portal vein injection (e.g., Figure 5; Figures 10-12; column 7, lines 51-61; column 8, lines 23-38; etc.). It is noted that Podsakoff et al. show that the AAV-ApoE/hAAT-hGC vector injected by tail vein injection resulted in the expression of hGC 4 weeks after the injection (e.g., see Figure 11 and column 8, lines 29-34).

Wakita specifically teaches that conditional transgene expression of nucleic acids encoding HCV E1 and HCV E2 in the liver of a transgenic mouse results in an animal that can be used as a powerful tool to investigate the immune responses and pathogenesis of HCV infection.

Lee teaches that the p214K9 is an immunodominant HCV-specific CTL-epitope. Specifically, Lee teaches that DNA that expresses p214K9 can be used to stimulate cytotoxic T cells specific for p214K9 epitope.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of filing that an animal having tolerance to an HCV gene (i.e., p214K9) can be made by delivering the adeno-associated viral particle that has been modified to express p214K9 to the liver of the animal by portal injection, with a reasonable expectation of success.

One of ordinary skill in the art would have been motivated to combine the teachings based on the teaching of Wakita that an animal that expresses an HCV transgene in the liver of an animal results in an animal that is "a powerful tool with which to investigate the immunoresponses and pathogenesis of HCV infection" (see abstract of Wakita). Furthermore, one of ordinary skill would have been motivated to use the p214K9 peptide because Lee teaches that the p214K9 peptide can stimulate a CTL immune response specific for p214K9 peptide.

Additionally, it would have been recognized that portal injection of a vector that expresses a protein is an easier way of producing the animal that expresses a foreign gene than making a transgenic animal, as was done by Wakita.

Response to Arguments

5. The amendment obviates the previous rejection(s). Therefore, the rejection has been withdrawn. However, upon consideration of the newly amended claims, a new ground(s) of rejection is made in view of Lee et al, cited by Applicants in the 12/18/2008 IDS, for the reasons set forth herein.

It is noted that the rejection of claims under 35 U.S.C. 103 is based on Lee et al., which is applicable as prior art only under 35 U.S.C. 102(a) (i.e. Lee was published less than 1 year prior to the instant effective filing date and different entity). Thus, Applicants may overcome the instant rejection by filing a proper Declaration under 35 U.S.C. 1.131 or 1.132.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner, Art Unit 1635